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EXAMINER	
EWOLDT, GERALD R	

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1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,541	STRAND ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 12/16/08 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment, remarks, and IDS filed 12/16/08 have been entered.

2. Newly added Claims 84-104 are under examination.

3. In view of Applicant's amendment, the previous rejections under 35 U.S.C 102 and 112 first paragraph have been withdrawn.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. New Claims 84-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-64 of U.S. Patent No. 7,081,242 in view of Wallace, D.J. (2001, IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '242 patent encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2. Wallace teaches the assessing of patients for anti-ds-DNA K_D level and restricting the administering of the composition

to patients with high affinity anti-ds-DNA wherein greater efficacy of treatment could be achieved.

Applicant argues that the '242 patent does not disclose all of the limitations of the new claims.

It would be reasonably obvious to a physician to administer a drug followed by an assessment of the drug's effects wherein only those patients displaying efficacy would be continued on the specific treatment, particularly when the claimed method is considered in view of Wallace. Accordingly, the method of the new claims is obvious.

6. New Claims 84-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 27, 31, 36, 41, and 44-58 of U.S. Patent Application No. 10/814,555 in view of Wallace, D.J. (2001, IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '555 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. New Claims 84-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-14 of U.S. Patent Application No. 11/081,309 in view of Wallace, D.J. (2001, IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '309 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. New Claims 84-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 56-121 of U.S. Patent Application No. 11/373,699 in view of Wallace, D.J. (2001, IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '699 application encompass a method of treating SLE employing LJP-394

comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. New Claims 84-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-26 of U.S. Patent Application No. 11/565,467 in view of Wallace, D.J. (2001, IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '467 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. New Claims 84-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-39 of U.S. Patent Application No. 11/562,174 in view of Wallace, D.J. (2001, IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '987 application encompass a method of treating SLE employing LJP-394 comprising SEQ ID NOS:1 and 2.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Regarding sections 6-10 above, Applicant requests that the rejections be held in abeyance.

The rejections have been maintained for the reasons set forth above. Applicant is advised that should the claims in the instant application be found allowable after final rejection Applicant's response to these pending rejections at that time will be considered to be a new issue and will not be considered by the Examiner after final rejection.

11. The following are new grounds for rejection.

12. New Claims 84-104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 11 of U.S. Patent No. 5,552,391 in view of Wallace, D.J. (2001, IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '391 patent encompass a method of treating SLE employing LJP-394 (see particularly Figure 6). Wallace teaches the assessing of patients for anti-ds-DNA and restricting the administering of the composition to patients with high affinity anti-ds-DNA wherein greater efficacy of treatment could be achieved.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 84-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, the recitation of "assessing level of circulating anti-ds-DNA antibodies" is vague and indefinite because first, the claim should read, "assessing the level of…" and second, it is not disclosed what level is assessed, e.g. antibody titer level, antibody K_D level, etc.

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 84-104 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification does not enable the claimed method wherein patient's are selected for treatment based on a reduction in antibody level wherein said level encompasses antibody serum titer.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. With these teachings in mind, an enabling disclosure, commensurate in scope with the breadth of the claimed invention, is required.

A review of the specification reveals no showing of treatment efficacy based on selecting patients who display a reduction in anti-ds-DNA antibody levels (titer). Indeed, the major antibody parameter measured in the methods of the instant specification is antibody affinity (K_D). More importantly, Inventor Linnik disclosed in WO 01/41813 that, "In view of our analysis, neither these initial reported titers or changes in titers were predictive of clinical outcome" (page 10). The Inventor went on to show that a reduction in anti-ds-DNA antibody affinity was the only relevant factor in achieving efficacious treatment. Wallace (2001, IDS) reviews the findings of Inventor Linnik and teaches that it was the Inventor's reevaluation of the results of failed LJP-394 trials that led the Inventor to his conclusion (page 115).

For these reasons the method of the instant claims would require undue experimentation to be used as claimed to effectively stabilize or improve the health-related quality of life in an SLE patient as is recited in the claims.

17. Claims 84-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter written description rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the methods of Claims 84 and 99 comprising the specific "assessing" step of part (b) and, additionally, a method wherein the treatment is only continued in an individual displaying a sustained reduction in antibody level as in part (d).

Applicant cites some 50+ paragraphs in support of the new claims.

None of the cites disclose the specific method steps of parts (b) and (d). Further, nowhere in the specification is it disclosed that a sustained reduction in antibody level can be used as a requirement for continued treatment.

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 84-104 rejected under 35 U.S.C. 103(a) each as being unpatentable over WO 01/41813 (IDS) in view of Wallace, D.J, (2001, IDS).

WO 01/41813 teaches a method of stabilizing or improving the health-related quality of life of an individual with SLE comprising administering LJP-394 at a dose of about 5-100mg/kg,

or about 200-500 mg (see particularly page 40). LJP-394 comprises the dsDNA epitope of SEQ ID NO:1 and SEQ ID NO:2 conjugated to the valency platform of Claim 71 (see particularly the Claims). The reference teaches the additional limitations of the claims including sustained reduction of symptoms for at more than about 16 or 24 weeks, or a year (Figures 14 and 15). The figures also show an at least about 20% or 30% reduction below baseline.

The reference differs from the claimed invention only in that it does not teach the assessing step of part (b) and the continuation of treatment only in patients wherein a reduced antibody level is achieved (step (d)).

Wallace teaches the assessing of patients for anti-ds-DNA K_D level and restricting the administering of the composition to patients with high affinity anti-ds-DNA wherein greater efficacy of treatment could be achieved.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the SLE treatment method of WO 01/41813 and to continue the treatment only on patients for whom the treatment was effective. Wallace teaches that those patients would be patients who displayed a reduced level of antibody affinity level for ds-DNA. The ordinarily skilled artisan would have continued treatment only on patients for whom it was effective to both save expense and reduce possible side effects or drug interaction.

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, Ph.D. can be reached on (571) 272-0878.

22. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information

about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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